

09/055,744



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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
09/055,744	04/07/98	SIA	C 1038-746-MIS

EXAMINER
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HM22/0410

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AIR MAIL  
DATE MAILED:  
04/10/01

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

### OFFICE ACTION SUMMARY

Responsive to communication(s) filed on 1-3-01

- This action is FINAL.  
 Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three (3) month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- Claim(s) 1, 3-15 is/are pending in the application.  
 Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 Claim(s) \_\_\_\_\_ is/are allowed.  
 Claim(s) 1, 3-15 is/are rejected.  
 Claim(s) \_\_\_\_\_ is/are objected to.  
 Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.  
 The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.  
 The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.  
 The specification is objected to by the Examiner.  
 The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).  
 All  Some\*  None of the CERTIFIED copies of the priority documents have been received.  
 received.  
 received in Application No. (Series Code/Serial Number) \_\_\_\_\_  
 received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- Notice of Reference Cited, PTO-892  
 Information Disclosure Statement(s), PTO-1449, Paper No(s). 17  
 Interview Summary, PTO-413  
 Notice of Draftsperson's Patent Drawing Review, PTO-948  
 Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES-

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicant's request for a Continuing Prosecution Application is acknowledged. Accordingly, FINALITY of the last Office Action 5 is withdrawn.

The Examiner acknowledges Applicant's Amendment, Paper No. 15, filed January 3, 2001. In view of Applicant's Amendment, the status of the claims is as follows: Claim 2 has been canceled; 10 Claims 1 and 3-15 are currently pending before the Examiner. It is noted that Applicant's amendment requested cancellation of both claims 2 and 7 (see Paper No. 15, page 1). However, it is also noted that Applicant provided an amended claim 7 (see page 1, last three lines). It is also noted that claim 3 has not been canceled by Applicant although Applicant's Remarks indicate such (see Paper 15 No. 15, page 3, fifth full paragraph). The Examiner has treated Applicant's request for cancellation of claim 7 as a typographical error in view of the submitted amended claim and has included amended claim 7 in the currently pending claims. Claim 3 also remains pending in the absence of a clear instruction to cancel it. 20 **Applicant is required to clarify these inconsistencies in response to this Office Action.**

The Examiner acknowledges Applicant's submission of a properly completed Form PTO-1449, Paper No. 17, filed January 3, 2001. A copy of the initialed, signed and dated PTO-1449 is attached to 25 this Office Action. The Examiner regrets any inconvenience on Applicant's part in perfecting Applicant's Information Disclosure Statement.

The Examiner acknowledges Applicant's submission of a new Oath and Declaration, Paper No. 16, filed January 3, 2001. Applicant's 30 new Oath is acceptable.

Claims 3 and 6-15 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 3 is vague and indefinite in the recitation "claim 2" since a claim cannot depend from a canceled claim. Amendment of claim 3 to correct the dependency or take other appropriate action would obviate this rejection. Claim 3 is further vague and indefinite in the recitation "T-helper epitopes" since the claim language lacks antecedent basis. Amendment of claim 3 to provide proper antecedent basis for the claim language "T-helper epitopes" would obviate this rejection. Claim 6 is vague and indefinite in the recitation "having an amino acid sequence which is that of a portion of an HIV-1 antigen and containing at least one T-cell epitope" since it is unclear if the limitation "containing at least one T-cell epitope" is intended to be a limitation of the T-cell inducing molecule but separate from the amino acid sequence or, rather, that the T-cell epitope is an integral part of the amino acid sequence itself. Amendment of claim 6 to more clearly point out and define what is intended to be encompassed by the claimed subject matter would obviate this rejection. Claim 7 is vague and indefinite in the recitation "said peptide having an amino acid sequence...of the Rev protein of HIV-1" since the language lacks antecedent basis in claim 5 or ultimately in claim 1. Amendment of claim 7 to provide proper antecedent basis would obviate this rejection. Claims 6-7 are further vague and indefinite in the recitation "having an amino acid sequence which is that of a portion..." since it is entirely unclear what is encompassed within the metes and bounds of the claim language "that of a portion of...." Amendment of claims 6-7 to more particularly point out and define what is intended to be encompassed within the metes and bounds of the claim language "that of a portion..." would obviate this rejection. Claim 12 is vague and indefinite in the recitation "an amino acid corresponding to" since it is unclear in what way and to what degree the amino acid

sequence "corresponds to" the amino acid sequence of the Rev protein. Amendment of claim 12 to delete "an amino acid corresponding to" would obviate this rejection.

Claims 1 and 3-15 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention for the reasons of record set forth in the last Office Action. Applicant's arguments have been fully considered but are not deemed persuasive to overcome the rejection. Applicant has reiterated previous arguments that "Applicants have provided a sound immunization protocol for inducing a HIV-specific cytotoxic T-cell response in a host" (see Paper No. 15, page 4, first full paragraph). Applicant has further argued that "applicants' claims do not recite HIV infection therapy nor prevention [sic] of infection" (see Paper No. 15, page 4, last paragraph). This is not persuasive.

As stated in the last Office Action, Applicant has not provided any convincing objective evidence to support the assertion of enablement or to rebut the Examiner's objective evidence of non-enablement as evidenced by the teachings of Fahey et al., Fox, and Haynes as set forth in the last Office Action. As stated previously, Applicants have not provided any convincing evidence that their claimed invention is indeed useful as a therapeutic or preventative for HIV infection and have not provided sufficient guidance to allow one skilled in the art to practice the claimed invention with a reasonable expectation of success and without undue experimentation. With respect to Applicant's arguments with regard to the treatment and/or prevention of HIV infection, it is clear from Applicant's specification that the claimed invention is intended to encompass vaccine therapeutics for HIV infection. Indeed, the entire "Background of the invention" section of

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Applicant's disclosure indicates that Applicant intended invention is directed to HIV vaccines. Applicant's disclosure specifically states "The present effort has turned to the design of HIV vaccines capable of eliciting cell-mediated immunity (CMI) and protocols for the use thereof" (see specification, page 2, first full paragraph). If Applicant does not intend for the scope of the instantly claimed invention to encompass vaccines and immunization protocols for HIV vaccines as set forth in the specification, such limitations should be clearly set forth in the claim language.

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Further, as stated previously, Applicant's data is only directed to methods using MHC Class I HLA A2 molecules. Applicant admits on the record that the present invention is based on a few limited oligopeptides, CLP-177, CLP-72, CLP-178 and CLP-182, as well as a long peptide (SEQ ID NO: 9) which were capable of binding to an HLA class I molecule, A2 (see Paper No. 15, paragraph bridging pages 3-4). There are no teachings in the specification of other peptides which could bind with HLA A2 and stimulate an anti-HIV cell-mediated immune response nor is there any evidence of other peptides which could bind to other HLA class I molecules. As evidenced by the teachings of Falk et al. and Deng et al. (see Applicant's Information Disclosure Statement, Paper No. 17, items 2 and 6), there are numerous HLA class I molecules each having its own particular consensus motif for binding oligopeptides (see Falk et al., Abstract). Further, as evidenced by Deng et al., even peptides that do bind to a particular HLA class I molecule, do not necessarily elicit satisfactory immune responses. Deng et al. discovered that while they could identify ten peptides which would bind to MHC K<sup>d</sup> (a mouse class I histocompatibility molecule analogous to the HLA class I molecules in humans), only five of the peptides elicited a secondary CD8+ response (see Abstract). Thus, the evidence of Falk et al. and Deng et al. establish the unpredictable nature of identifying oligopeptides suitable for binding to HLA class I molecules and capable of eliciting immune

responses.

Further, as stated previously with respect to HLA class II molecules (see claim 3), Class I and Class II molecules differ in their structures and immunological specificities and it is unclear from the evidence of the specification that the two types of molecules can be used interchangeably in the claimed methods using the claimed peptides. Further, MHC restriction and regulation of the immune system may well limit the use of T helper molecules to a particular haplotype for a particular individual, analogous to tissue typing for transplantation antigens. In other words it is unclear that the claimed method utilizing a DR7 molecule would satisfactorily stimulate a CTL response in a DR4 individual. Stimulating specific T cell responses to a particular epitope is unpredictable.

In the absence of any convincing objective evidence to the contrary, one skilled in the art would not be able to make and use the claimed invention throughout its scope with a reasonable expectation of success and without undue experimentation. Therefore, the rejection is deemed proper and is maintained.

No claim is allowed.

Papers relating to this application may be submitted to Group 1600 by facsimile transmission. The Fax number is (703) 308-4242. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 25 1989).

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Robert D. Budens at (703) 308-2960. The Examiner can normally be reached Monday-Thursday from 6:30 AM-4:00 PM, (EST). The Examiner can also

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be reached on alternate Fridays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, James Housel, can be reached at (703) 308-4027.

5 Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist at (703) 308-0196.



Robert D. Budens  
Primary Examiner  
Art Unit 1648

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rdb  
April 8, 2001